#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Go Watanabe; Yoshiki

Sawa; and Satoshi Taketani

Examiner: Sarah K. Webb

Serial No.: 10/550,819

Art Unit: 3731

Filed: June 21, 2006

Attorney Docket: 49288.1500

Title: SURGICAL HOLDER FOR A BLOOD VESSEL

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#### **APPEAL BRIEF**

Appellant submits this brief pursuant to 37 C.F.R. §41.37 and with the required fee under 37 C.F.R. § 41.20(b)(2), appealing the final rejection of the claims of the above-identified application in a final Office Action (the "Office Action") mailed November 22, 2010.

Appellant hereby petitions that the period to take action in the above-captioned application be extended as necessary and is hereby authorize any necessary extension fee, as well as the required appeal fee, or credit any overpayment to be charged or credited to Deposit Account No. 19-2814.

### I. REAL PARTY IN INTEREST.

The real parties in interest in this appeal are Cardio Incorporated and Go Watanabe, the assignees of the present application.

## II. RELATED APPEALS AND INTERFERENCES.

There are no related appeals or interferences known to the Appellant or the Appellant's legal representative that will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

## III. STATUS OF CLAIMS.

Claims 1-3, 5-7, 9, 10, 12-14, and 18-29 are pending in this application, are subject to this appeal, and are reproduced in the Claims Appendix. Claims 4, 8, 11, and 15-17 are cancelled. The pending claims stand finally rejected as follows:

- (1) Claims 1, 5-7, 9, 10, 12-14, and 18-19 are rejected under 35 U.S.C.§ 102(b) as being anticipated by U.S. Patent No. 6,234,448 ("Porat").
- (2) Claim 2 and 3 are rejected as being unpatentable under 35 U.S.C. § 103(a) over *Porat* in view of U.S. Patent Application Pub. No. 2002/0177863 ("Mandel").

## IV. STATUS OF AMENDMENTS.

There are no pending, unentered amendments.

### V. SUMMARY OF CLAIMED SUBJECT MATTER.

Reference herein to portions of the specification and figures are exemplary only and refer to the Application as published (Pub. No. 2006/0259056).

Independent claim 1 is directed to a surgical holder (e.g., surgical holder H in Figure 1). See Application, ¶[0063]. The surgical holder comprises a grasping member for grasping a tubular tissue (e.g., grasping member 1), a manipulation member for manipulating the grasping member (e.g., manipulation member 2), and a connection portion with one end connected to the manipulation member (e.g., wiring portion 3). See Application, ¶[0063] and Figure 1. The grasping member includes a first grasping plate (e.g., first grasping plate 6) and a second grasping plate (e.g., second grasping plate 8) provided so as to oppose the first grasping plate in a movable manner so that they are able to become closer to each other or more distanced from each other. See Application, Figures 2-7 and ¶¶[0064]-[0066]. The first grasping plate includes a retaining portion (e.g., retaining portion 18) having an opening (e.g., opening 14) which is opened toward a first outer side of the first grasping plate and a supporting portion (e.g., supporting portion 22) having a recessed portion (e.g., recessed portion 20) which extends towards a second outer side of the first grasping plate, the first outer side being opposed to the second outer side and the opening being of a U-shape or substantially a U-shape. See Application, ¶¶[0067]-[0069] and Figures 2-7. The retaining portion includes two edge portions (e.g., edge portions 16) each having an elongated end portion, the two edge portions together forming the peripheral portion of the opening to define the shape of the opening, and the end

portion of the edge portion having a length and being configured to be inserted into a tube of the tubular tissue for grasping the tubular tissue. See Application,  $\P[0069]$ -[0070] and Figure 2. The second grasping plate (e.g., second grasping plate 8) includes a covering portion (e.g., covering portion 26) formed so as to cover an entire surface or a part of the opening of the first grasping plate, a non-covering portion (e.g., non-covering portion 28) which does not cover the first grasping plate, and a fixing portion (e.g., fixing portion 23) having a curved portion (e.g., curved portion 24), the covering portion being provided in one end of the second grasping plate and the curved portion being provided in the other end of the second grasping plate, the curved portion opposing the recessed portion to form a generally tubular tissue grasping space for grasping the tubular tissue when the first grasping plate and the second grasping plate are positioned so as to oppose one another. See Application, ¶[0078] and Figures 2, 3, and 8. The surgical holder further includes a first grasping portion which can grasp a part of the tubular tissue between the retaining portion of the first grasping plate and the covering portion of the second grasping plate are provided in one end portion of the grasping member, and the opening exposing another part of the tissue when a part of the tubular tissue is grasped by the first grasping portion. See Application, ¶[0070]. A second grasping portion which can form the tissue grasping space for the tubular tissue between the recessed portion of the first grasping plate and the curved portion of the second grasping plate is provided in another end portion of the grasping member. See Id.

Independent claim 5 is directed to a surgical holder (e.g., surgical holder H in Figure 1) comprising a grasping member for grasping a tubular tissue (e.g., grasping member 1), a manipulation member for manipulating the grasping member (e.g., manipulation member 2), and a connection portion (e.g., wiring portion 3) with one end connected to the manipulation member and the other end provided with a fixing tool (e.g. fixing tool 33). See Application, ¶¶[0063] and [0099], and Figure 1. The grasping member includes a first grasping plate (e.g., first grasping plate 6) and a second grasping plate (e.g., second grasping plate 8) provided so as to oppose the first grasping plate in a movable manner so that they are able to become closer to each other or more distanced from each other. See Application, Figures 13-14, ¶¶[0064]-[0066] and [0116]-[0119]. The grasping member is formed into a rectangular shape with the manipulation member elongated from a side thereof. See Application, Figures 13-14 and ¶¶[0116]-[0119]. The surgical holder further includes a first grasping portion which can grasp a part of the tubular tissue between the first grasping plate and the second grasping plate, and an opening (e.g., opening 14) which is provided in the vicinity of the first grasping portion and exposes another part of the tissue are provided in one end portion of the grasping member, the opening being opened at a first outer side of the first grasping portion and the opening being of a U-shape or substantially a U-shape. See Id. The first grasping plate includes two edge portions (e.g., edge portions 16) each having an elongated end portion, the two edge portions together forming the peripheral portion of the opening to define the shape of the opening, and the end portion of the edge portion having a length and being configured to be inserted into a tube of the tubular tissue

for grasping the tubular tissue. *See* Application, ¶[0080]. A second grasping portion which can form a generally tubular tissue grasping space (*e.g.*, tissue grasping space 15) for the tubular tissue between the first grasping plate and the second grasping plate is provided in another end portion of the grasping member, the tissue grasping space and the opening being positioned at opposing ends on one axis of the grasping member. *See* Application, ¶¶[0113]-[0114] and Figures 12A, 12B, 13, and 14.

Independent claim 6 is directed to a surgical holder (e.g., surgical holder H) comprising a grasping member for grasping a tubular tissue (e.g., grasping member 1), a manipulation member for manipulating the grasping member (e.g., manipulation member 2), and a connection portion connected to the manipulation member (e.g. wiring portion 3). See Application, ¶[0063] and Figure 1. The grasping member includes a first grasping plate (e.g., first grasping plate 6) and a second grasping plate (e.g., second grasping plate 8) provided so as to oppose the first grasping plate in a movable manner so that they are able to become closer to each other or more distanced from each other. See Application, Figures 2-7 and ¶[0064]-[0066]. The first grasping plate includes a retaining portion (e.g., retaining portion 18) having an opening of a U-shape or substantially a U-shape, and a supporting portion (e.g., supporting portion 22) having a recessed portion (e.g., recessed portion 20), the opening being provided in a first end of the first grasping plate and the recessed portion being provided in a second end of the first grasping plate, the first and second ends of the first grasping plate being opposed to each other. See Application, ¶[0067]-[0069] and Figures 2-7. The first grasping plate includes two edge portions (e.g., edge

portions 16) each having an elongated end portion, the two edge portions together forming the peripheral portion of the opening to defines the shape of the opening, the end portion of the edge portion having a length and being configured to be inserted into a tube of the tubular tissue for grasping the tubular tissue. *See Id.* The second grasping plate includes a covering portion (*e.g.*, covering portion 26) formed to cover an entire surface or a part of the opening of the first grasping plate, a non-covering portion (*e.g.*, non-covering portion 28) which does not cover the first grasping plate, and a fixing portion (*e.g.*, fixing portion 23) having a curved portion (*e.g.*, curved portion 24), the curved portion opposing the recessed portion to form a generally tubular tissue grasping space for grasping the tubular tissue when the first grasping plate and the second grasping plate are positioned so as to oppose one another. *See* Application, ¶[0078] and Figures 2, 3, and 8.

## VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL.

The issues for consideration in this appeal are:

- A. Whether the Examiner erred in rejecting claims 1, 5-7, 9, 10, 12-14, and 18-19 under 35 U.S.C.§ 102(b) as being anticipated by *Porat*.
- B. Whether the Examiner erred in rejecting claims Claim 2 and 3 as being unpatentable under 35 U.S.C. § 103(a) over *Porat* in view of *Mandel*.

#### VII. ARGUMENT.

## A. Rejections under 35 U.S.C §102 Over Porat.

For the Examiner to establish a *prima facie* case of anticipation under 35 U.S.C. §102, it is well settled that the Examiner must demonstrate "the presence in a single prior art reference disclosure of each and every element of the claimed invention, <u>arranged as in the claim."</u> *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458

(Fed. Cir. 1984)(emphasis added). Appellant respectfully asserts that the Office Action has not met this test.

The Examiner asserts that *Porat* discloses a device that includes all the claimed structured features and is "capable of" being used as a surgical holder for grasping tissue.

Specifically, the Examiner alleges that the "U-shaped opening (56)" in *Porat*'s device "has a pair of elongated edge portions (60) that are capable of being inserted into a tubular tissue," thus corresponding to the claimed "elongated edge portions" which together define the "opening" in the "first grasping plate" of the present invention.

Furthermore, the Examiner simply ignores, and therefore fails to properly give weight to, the limitations of the rejected claims. *See, e.g.*, Advisory Action mailed January 14, 2011 ("The requirement that the edge portions be configured for insertion into a tubular tissue for grasping tissue is a broad functional limitation without much weight" ... "any limitations regarding the tissue are not given patentable weight."). However, these limitations <u>do</u> patentably distinguish the claimed invention from the cited art because they define the structure of the claimed surgical

holder using functional limitations that "must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used." MPEP §2173.05(g).

In any event, *Porat* does not disclose or contemplate that the "portion (60)" is "configured to be inserted into a tube of the tubular tissue for grasping the tubular tissue," as required by the claimed "elongated edge portions." According to *Porat*, the portion (60) in the reference device is called a "catch arm," which has at least one catch member (62) arranged thereon for engaging with a latching means (53), in order that the device ("clamp (10)") can pinch a tubing (90) about its external circumferential surface. *See, e.g.*, Figs. 2-9 and the associated description at column 9, lines 24-35 and column 10, lines 57-63 provided by *Porat*. As such, Appellant asserts that it is <u>not</u> evident how the "catch arm (60)" in *Porat*'s clamp device would be "capable of" inserting into a tubular tissue for grasping the tubular tissue, like the claimed "elongated edge portion."

Since the aim of *Porat* is to "provide a pinch clamping device which may be laterally mounted <u>onto</u> a length of the tubing" (column 2, lines 13-15), Appellant asserts that *Porat* <u>teaches away from</u> the claimed invention. In this regard, Appellant asserts that one skilled in the art would not be remotely motivated to modify *Porat*'s pinch clamp for grasping a tubular tissue by inserting a part thereof <u>into</u> the tubular tissue, as currently claimed.

In addition to *Porat*'s failure to disclose or even suggest the limitations of the claimed invention, The Office Action provides no support for the contention that *Porat* is "capable of"

the limitations of the claimed invention. Appellant respectfully submits that it is well-settled that where a reference is alleged to inherently disclose a claim limitation, the missing limitation must necessarily be present in the cited reference. It is insufficient that the missing limitation is "merely probably or possibly present" in the cited art. *Trintect Industries, Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292 at 1295 (Fed. Cir. 2002); *see W.L. Gore v. Garlock, Inc.*, 721 F.2d at 1554 (Fed. Cir. 1983) (anticipation "cannot be predicated on mere conjecture respecting the characteristics of products that might result from the practice of processes disclosed in references"); *see also In re Oelrich*, 666 F.2d 578 at 581 (CCPA 1982) (to anticipate, the asserted inherent function must be present in the prior art); *see also In re Robertson*, 169 F.3d 743 at 745 (Fed. Cir. 1999) (that a feature in the prior art reference "could" operate as claimed does not establish inherency).

Thus, because *Porat* does not disclose each and every element of the claimed invention, arranged as in claims 1, 5-7, 9-10, 12-14 and 18-29, Appellant asserts that *Porat* does not anticipate the claims.

## B. Rejections under 35 U.S.C §103 Over Porat in view of Mandel.

The Examiner next rejects claims 2 and 3 under 35 U.S.C. §103(a) as being obvious over *Porat* in view of *Mandel*. Appellant respectfully disagrees. As discussed above, *Porat* fails to disclose or contemplate the claimed "elongated end portions" which are "configured to be inserted into a tube of the tubular tissue for grasping the tubular tissue", as recited in claim 1 (from which claims 2 and 3 depend). Appellant asserts that *Mandel* fails to remedy the

aforementioned deficiencies of *Porat*. Specifically, as Appellant pointed out in the previously submitted arguments, *Porat* merely pertains to a chevron shaped ligating clip which bears little structural resemblance with the claimed subject matter, or *Porat*'s pinch clamp. *See, e.g.*, Figs. 1 and 2 provided by *Mandel*.

Moreover, Appellant asserts that it appears that the Examiner has only relied on *Mandel* for the purported teaching of an antimicrobial and/or antibiotic coating to the clip surfaces, namely the features recited in pending claims 2 and 3. Appellant asserts that the combination of *Porat* and *Mandel* accordingly still fails to disclose or contemplate all the essential structural features of the claimed invention.

Furthermore, Appellant asserts that the novel structural features of the claimed invention also attain significant effects over the cited references. In particular, as Appellant emphasized in the previously submitted arguments, the claimed invention provides multiple ways to safely grasp a tubular tissue, including: (1) grasping a tubular tissue by inserting an "elongated end portion" of a first grasping plate into said tubular tissue and further moving the second grasping plate close to the first grasping plate to grasp the tissue more stably (e.g., Example 4 at [00141] in the specification and Figure 11); and (2) using the retaining portion of the first grasping plate and the covering portion of the second grasping plate to grasp a tubular tissue at one point, and using the tissue grasping space formed by the recessed portion of the first grasping plate and the curved portion of the second grasping plate at another point, to stably grape the tubular tissue (Example 3 at [00139] in the specification and Figure 10). By contrast, neither *Porat* nor

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Mandel teach a surgical holder for grasping a tubular tissue using the insertion means (1) as previously discussed, let alone a structure that provides two means (1) and (2) to grasp a tubing.

In view of the foregoing, Appellant asserts that the claimed invention is not anticipated or rendered obvious by the cited references.

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## VIII. CONCLUSION.

For the foregoing reasons, the pending claims are non-obvious and patentable, and Appellant respectfully requests that the Board reverse the rejections in the Office Action.

Respectfully submitted,

Date: April 7, 2010

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#### **CLAIMS APPENDIX**

1. (Previously presented) A surgical holder comprising a grasping member for grasping a tubular tissue, a manipulation member for manipulating the grasping member, and a connection portion with one end connected to the manipulation member, wherein:

the grasping member includes a first grasping plate, and a second grasping plate provided so as to oppose the first grasping plate in a movable manner so that they are able to become closer to each other or more distanced from each other;

the first grasping plate includes a retaining portion having an opening which is opened toward a first outer side of the first grasping plate and a supporting portion having a recessed portion which extends towards a second outer side of the first grasping plate, the first outer side being opposed to the second outer side and the opening being of a U-shape or substantially a U-shape, the retaining portion includes two edge portions each having an elongated end portion, the two edge portions together forming the peripheral portion of the opening to define the shape of the opening, and the end portion of the edge portion having a length and being configured to be inserted into a tube of the tubular tissue for grasping the tubular tissue,

the second grasping plate includes a covering portion formed so as to cover an entire surface or a part of the opening of the first grasping plate, a non-covering portion which does not cover the first grasping plate, and a fixing portion having a curved portion, the covering portion being provided in one end of the second grasping plate and the curved portion being provided in the other end of the second grasping plate,

the curved portion opposing the recessed portion to form a generally tubular tissue grasping space for grasping the tubular tissue when the first grasping plate and the second grasping plate are positioned so as to oppose one another,

a first grasping portion which can grasp a part of the tubular tissue between the retaining portion of the first grasping plate and the covering portion of the second grasping plate are provided in

one end portion of the grasping member, and the opening exposing another part of the tissue when a part of the tubular tissue is grasped by the first grasping portion; and a second grasping portion which can form the tissue grasping space for the tubular tissue between the recessed portion of the first grasping plate and the curved portion of the second grasping plate is provided in another end portion of the grasping member.

- 2. (Previously Presented) A surgical holder according to claim 1, wherein a tissue protection material is attached to at least one of: a side of the first grasping plate which opposes the second grasping plate, or a side of the second grasping plate which opposes the first grasping plate.
- **3.** (**Original**) A surgical holder according to claim 2, wherein the tissue protection material is permeated with medicines.

#### 4. (Canceled).

**5.** (**Previously presented**) A surgical holder comprising a grasping member for grasping a tubular tissue, a manipulation member for manipulating the grasping member, and a connection portion with one end connected to the manipulation member and the other end provided with a fixing tool, wherein:

the grasping member includes a first grasping plate, and

a second grasping plate provided so as to oppose the first grasping plate in a movable manner so that they are able to become closer to each other or more distanced from each other;

the grasping member is formed into a rectangular shape with the manipulation member elongated from a side thereof;

a first grasping portion which can grasp a part of the tubular tissue between the first grasping plate and the second grasping plate, and an opening which is provided in the vicinity of the first grasping portion and exposes another part of the tissue are provided in one end portion

of the grasping member, the opening being opened at a first outer side of the first grasping portion and the opening being of a U-shape or substantially a U-shape;

the first grasping plate includes two edge portions each having an elongated end portion, the two edge portions together forming the peripheral portion of the opening to define the shape of the opening, and the end portion of the edge portion having a length and being configured to be inserted into a tube of the tubular tissue for grasping the tubular tissue,

a second grasping portion which can form a generally tubular tissue grasping space for the tubular tissue between the first grasping plate and the second grasping plate is provided in another end portion of the grasping member, the tissue grasping space and the opening being positioned at opposing ends on one axis of the grasping member.

6. (Previously presented) A surgical holder comprising a grasping member for grasping a tubular tissue, a manipulation member for manipulating the grasping member, and a connection portion connected to the manipulation member, wherein:

the grasping member includes a first grasping plate and a second grasping plate provided so as to oppose the first grasping plate in a movable manner so that they are able to become closer to each other or more distanced from each other;

the first grasping plate includes a retaining portion having an opening of a U-shape or substantially a U-shape, and a supporting portion having a recessed portion, the opening being provided in a first end of the first grasping plate and the recessed portion being provided in a second end of the first grasping plate, the first and second ends of the first grasping plate being opposed to each other;

the first grasping plate includes two edge portions each having an elongated end portion, the two edge portions together forming the peripheral portion of the opening to defines the shape of the opening, the end portion of the edge portion having a length and being configured to be inserted into a tube of the tubular tissue for grasping the tubular tissue, and

the second grasping plate includes a covering portion formed to cover an entire surface or a part of the opening of the first grasping plate, a non-covering portion which does not cover the first grasping plate, and a fixing portion having a curved portion, the curved portion opposing the recessed portion to form a generally tubular tissue grasping space for grasping the tubular tissue when the first grasping plate and the second grasping plate are positioned so as to oppose one another.

7. (Previously presented) A surgical holder according to claim 6, wherein a surrounding tissue of the tubular tissue is grasped by the edged portion and the covering portion of the second grasping plate.

#### 8. (Cancelled).

- 9. (Previously presented) A surgical holder according to claim 6, wherein the tubular tissue is grasped with one point of the tubular tissue being grasped by the retaining portion of the first grasping plate and the covering portion of the second grasping plate, and another point being grasped by the tissue grasping space formed by the recessed portion of the first grasping plate and the curved portion of the second grasping plate.
- 10. (Previously presented) A surgical holder according to claim 6, wherein the edge portion is inserted into a tube of the tubular tissue to grasp the tubular tissue.

#### 11. (Canceled).

12. (Previously presented) A surgical holder according to claim 1, wherein the recessed portion provided is recessed toward a thickness of the first grasping plate.

- 13. (Previously presented) A surgical holder according to claim 5, wherein the generally tubular tissue grasping space is formed by a recessed portion on the first grasping plate and a curved portion on the second grasping plate, when the first grasping plate and the second grasping plate are positioned so as to oppose one another, and the recessed portion provided is recessed toward a thickness of the first grasping plate.
- 14. (Previously presented) A surgical holder according to claim 6, wherein the recessed portion provided is recessed toward a thickness of the first grasping plate.

### 15-17. (Cancelled)

- 18. (Previously presented) A surgical holder according to claim 1, wherein the first grasping plate and the second grasping plate are of flat plate shape, the curved portion is provided on a fixing portion which is provided to extend from the covering portion through an elongated piece, and the non-covering portion of a rectangular shape is formed by an edge of the covering portion, the elongated piece, and the fixing portion.
- 19. (Previously presented) A surgical holder according to claim 5, wherein the first grasping plate and the second grasping plate are of flat plate shape, the curved portion is provided on a fixing portion which is provided to extend from the covering portion through an elongated piece, and the non-covering portion of a rectangular shape is formed by an edge of the covering portion, the elongated piece, and the fixing portion.
- **20.** (**Previously presented**) A surgical holder according to claim 6, wherein the first grasping plate and the second grasping plate are of flat plate shape, the curved portion is provided on a fixing portion which is provided to extend from the covering portion through an elongated piece,

and the non-covering portion of a rectangular shape is formed by an edge of the covering portion, the elongated piece, and the fixing portion.

- 21. (Previously presented) A surgical holder according to claim 1, wherein the tubular tissue is a blood vessel.
- **22.** (**Previously presented**) A surgical holder according to claim 5, wherein the tubular tissue is a blood vessel.
- 23. (Previously presented) A surgical holder according to claim 6, wherein the tubular tissue is a blood vessel.
- **24.** (**Previously presented**) A surgical holder according to claim 1, wherein the recessed portion provided forms an indentation in a plane defined by the remaining portion of the first grasping plate, and the curved portion is raised relative to the remaining portion of the second grasping plate, to form the generally tubular tissue grasping space with the opposed recessed portion for grasping blood vessels.
- 25. (Previously presented) A surgical holder according to claim 5, the generally tubular tissue grasping space is formed by a recessed portion on the first grasping plate and a curved portion on the second grasping plate, when the first grasping plate and the second grasping plate are positioned so as to oppose one another, and wherein the recessed portion provided forms an indentation in a plane defined by the remaining portion of the first grasping plate, and the curved portion is raised relative to the remaining portion of the second grasping plate, to form the generally tubular tissue grasping space with the opposed recessed portion for grasping blood vessels.

- 26. (Previously Presented) A surgical holder according to claim 6, wherein the recessed portion provided forms an indentation in a plane defined by the remaining portion of the first grasping plate, and the curved portion is raised relative to the remaining portion of the second grasping plate, to form the generally tubular tissue grasping space with the opposed recessed portion for grasping blood vessels.
- 27. (Previously Presented) A surgical holder according to claim 1, wherein the two elongated edge portions form part of the peripheral portion of the first grasping plate.
- 28. (Previously Presented) A surgical holder according to claim 5, wherein the two elongated edge portions form part of the peripheral portion of the first grasping plate.
- 29. (Previously Presented) A surgical holder according to claim 6, wherein the two elongated edge portions form part of the peripheral portion of the first grasping plate.

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## **EVIDENCE APPENDIX**

None.

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# RELATED PROCEEDINGS APPENDIX

None.